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Application No.	Inventor	Class Name	Attorney	Agent
24,281	24,281	HEALTH	24,281-12	

Stephen A. Bent
Foley & Lardner Washington Harbor
Suite 500
3000 K Street, N.W.
Washington, DC 20007-5143

EXAMINER

KATCHEVES, KONSTANTINA I

APPLICANT	APPLICANT NAME
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DATE MAILED 07/29/2002

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Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10 029 281

Examiner

Konstantina Katcheves

Applicant(s)

PARK ET AL

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) and (b) but in no event more than SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the time period for reply is set to expire on the mailing date of this communication, the SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set time period may result in a statutory bar to the applicant's right to become ABANDONED (35 U.S.C. 111).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any available term adjustment (35 U.S.C. 154).

Status

- 1) ☐ Responsive to communication(s) filed on 20 May 2002
- 2a) ☐ This action is **FINAL**
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
a) ☐ All b) ☐ Some * c) ☐ None of:
1 ☐ Certified copies of the priority documents have been received.
2 ☐ Certified copies of the priority documents have been received in Application No. _____.
3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application):
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 2 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3 ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4 ☒ Interview Summary (PTO-413) Paper No(s) 5
- 5 ☐ Notice of Informal Patent Application (PTO-152)
- 6 ☐ Other _____

DETAILED ACTION

Claims 1-15 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a method for isolating DNA, classified in class 435, subclass 6.
- II. Claim 15, drawn to a liquid manure, classified in class 71, subclass 33.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the liquid manure claimed can be made by materially different chemical processes. Manures comprising sodium phosphate and sodium nitrate can be produced synthetically without the need to first isolate DNA from a cell. Therefore, the inventions of Groups I and II are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Art Unit 1636

During a telephone conversation with Ms. Kim on 23 July 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claim 15 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Response to Amendment

The rejection of claim 15 under 35 U.S.C. 112, first paragraph, is moot in view of the restriction requirement above.

The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of Applicant's Amendment filed 20 May 2002.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1636

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kresheck et al. (US Patent 5,625,053) in view of Pentecost et al. (Eur. J. Biochem. Vol. 195 No. 3 1991).

Applicant's invention is drawn to a method of isolating DNA from cells by disrupting squid or pollack spermatogonium, adding an alkaline solution, and adding an ethanol solution to precipitate the DNA.

Kresheck et al. teach a method wherein cells are lysed, an alkaline solution is added, and the DNA is precipitated from the resulting solution with a lower alcohol like methanol. Kresheck et al. also teach the limitations of claims 9 and 10 wherein the RNA is lysed with RNase. See columns 2, 4 and 5. Kresheck et al. fails to teach the method using fish spermatogonium. Kresheck et al. also fails to disclose that the cells were disrupted with a rotating-knife crusher or sonicator.

Pentecost et al. disclose the isolation and extraction of nucleic acids, specifically RNA, from fish spermatogonium. See abstract and page 4873.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize these purification techniques of Kresheck et al. to isolate DNA from various types of eukaryotic cells including fish spermatogonium, as disclosed in Pentecost et al. Kresheck et al. teach a method comprising the same steps claimed by Applicant. The ordinary skilled artisan would have been motivated to obtain the DNA from the above spermatogonium

Art Unit: 1636

for a multitude of reasons including sequencing, genetic modification and research, generally. Those of ordinary skill in the art have been isolating DNA from cells for many years such that one would reasonably expect the successful isolation of pollack and squid spermatogonium DNA as well. Additionally, claim 6 refers to other methods including physical disruption of cells by what one of ordinary skill in the art would recognize as a blender. One of ordinary skill in the art would recognize that these other methods could be used to lyse or disrupt cells. A blender, (i.e. a "rotating knife crusher") or a sonicator for lysing cells are not novel methods. The ordinary skilled artisan would have been motivated to combine the above teachings in a method for DNA isolation. Therefore, without evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kresheck et al. as applied to claims 1, 2 and 6-11 above, and further in view of Puig et al. (Biochimica et Biophysica Acta Vol. 1397 No. 1 1998).

Applicant's invention in the instant claims involves the acylation of protamines in the above method.

Kresheck et al. teach the elements of Applicant's invention as discussed above. However, Kresheck et al. fails to disclose the acylation through acetic anhydride of claims 3-5 and 12-14.

Puig et al. disclose the acetylation of the lysines in histone, H4, which cause the weakening of the attachment of the histone to the DNA. Applicant's method reads on

Art Unit: 1636

acetylation since the acylation reaction in the claim is mediated by the anhydride compound acetic anhydride.

It would have been obvious to one of ordinary skill in the art to combine the methods of Kresheck et al., that disclose the isolation of DNA, and the method of Puig et al., that disclose the acetylation of histones for the purposes of detaching them from DNA. The histones of Puig et al. like the protamines of the instant claims are proteins attached to DNA, which have a high lysine content. One of ordinary skill in the art would have been motivated to combine the teachings of Kresheck et al. and Puig et al. to arrive at Applicants inventions because acetylation of protamines, like histones, would cause the protamines to lose affinity with DNA thereby further purifying and isolating it. Therefore, without evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite the "lysis of RNA." This limitation is inherently confusing because one of skill in the art in practicing basic recombinant techniques understands that one lyses cells. Could applicant more appropriately mean "hydrolysis," which means the digestion, removal, or breakdown of RNA?

Art Unit: 1636

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
July 29, 2002



REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600